III. REMARKS

Claims 1-91 are pending.

A. Objections

Office has objected to Claims 19-93 and 50-93 as being misnumbered.

Applicant proposes amendments herein to Claims 19-91 to correct such informalities.

B. Claim Rejections under 35 U.S.C. 102

It is well settled that, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051 at 1053 (Fed. Cir. 1987); see also MPEP 2131.01.

1. Office has rejected Claims 1-3, 6-12, 14-16, 28, 31-33, 37-39, 42-48, 51, 52, 66-68, 72-75, 78-80, 86 and 87 under 35 U.S.C. 102(a) as being anticipated by Gao et al. (WO 00/32189).

Applicant respectfully traverses Examiner's rejection and asserts that the claims, as currently presented, are novel with respect to *Gao et al.* (WO 00/32189).

a. Independent Claim 1, Dependent Claims 2, 3, 6-12, 14-16, 28, and 31-33

Gao teaches orally deliverable celecoxib formulations capable of providing rapid relief from COX-2 mediated disorders. *Gao* does not teach "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 1-3, 6-12, 14-16, 28, and 31-33 of the present invention.

b. Independent Claim 37, Dependent Claims 38, 39, 42-48, 51, 52, and 66-68

Gao does not teach "a cellulosic polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 37-39, 42-48, 51, 52, and 66-68 of the present invention.

c. Independent Claim 72, Dependent Claims 73--75, 78-80, 86 and 87

Gao does not teach "a drug of low water solubility in a high energy phase" as required by Claims 72-75, 78-80, 86 and 87 of the present invention.

Gao also does not teach "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 72-75, 78-80, 86 and 87 of the present invention.

As *Gao* does not teach each and every element of the claims embracing the present invention, applicant requests withdrawal of the 35 U.S.C. 102(a) rejection.

2. Office has rejected Claims 1, 2, 7-10, 14-16, 27, 28, 31-38, 42-46, 51, 52, 62, 63, 66-72, 75, 77-80, 86 and 87 under 35 U.S.C. 102(a) as being anticipated by Tanida et al. (USPN 6,214,378).

Applicant respectfully traverses Examiner's rejection and asserts that the claims, as currently presented, are novel with respect to *Tanida et al.* (USPN 6,214,378).

Tanida discloses oral preparations having a capsule base coated with successive layers of a cationic copolymer and an anionic copolymer where a pharmacologically active substance is encapsulated in the capsules. The polymers present in *Tanida* retard disintegration until the capsule has reached the large intestine. Col.1, lines 53-64.

a. Independent Claim 1, Dependent Claims 2, 7-10, 14-16, 27, 28, and 31-36

Tanida does not teach "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 1, 2, 7-10, 14-16, 27, 28, and 31-36 of the present invention.

Tanida also does not teach a formulation wherein "at least a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid" as required by Claims 1, 2, 7-10, 14-16, 27, 28, and 31-36 of the present invention.

b. Independent Claim 37, Dependent Claims 38, 42-46, 51, 52, 62, 63, and 66-71

Tanida does not teach "a cellulosic polymer ...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 37, 38, 42-46, 51, 52, 62, 63, and 66-71 of the present invention.

Tanida also does not teach a formulation having "at least a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid" as required by Claims 37, 38, 42-46, 51, 52, 62, 63, and 66-71 of the present invention.

c. Independent Claim 72, Dependent Claims 75, 77-80, 86 and 87

Tanida does not teach "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 72, 75, 77-80, 86 and 87 of the present invention.

Tanida also does not teach "a drug of low water solubility in a high energy phase" as required by Claims 72, 75, 77-80, 86 and 87 of the present invention.

As Tanida does teach each and every element of the claims embracing the present invention, applicant requests withdrawal of the 35 U.S.C. 102(a) rejection.

3. Office has rejected Claims 1,2, 6-10, 14-16, 27, 28, 31-38, 42-46, 51, 52, 62, 63, 66-72, 75, 77-80, 86 and 87 under 35 U.S.C. 102(b) as being anticipated by Tanida et al. (WO 98/05310).

Applicant respectfully traverses Examiner's rejection and asserts that the claims, as currently presented, are novel with respect to *Tanida et al.* (WO 98/05310).

The analysis above (§III B-2) demonstrates that *Tanida* does not teach each and every element of the claims embracing the present invention. As such, Applicant requests withdrawal of the 35 U.S.C. 102(b) rejection.

4. Office has rejected Claims 1, 2, 6, 14-16, 21-24, 27, 28, 31, 32, 36-38, 42, 51, 52, 56-59, 62, 63, 66, 67, 71-73, 77-80, and 86-93 under 35 U.S.C. 102(b) as being anticipated by Black et al. (USPN 5,733,909).

The claims, as currently presented, are novel with respect to *Black et al.* (USPN 5,733,909).

a. Independent Claim 1, Dependent Claims 2, 6, 14-16, 21-24, 27, 28, 31, 32, and 36

Applicant respectfully traverses Examiner's rejection and asserts that the claims, as currently presented, are novel with respect to *Black et al.* (USPN 5,733,909).

Black does not teach "a drug of low water solubility" as required by Claims 1, 2, 6, 14-16, 21-24, 27, 28, 31, 32, and 36 of the present invention.

Black also does not teach "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 1, 2, 6, 14-16, 21-24, 27, 28, 31, 32, and 36 of the present invention.

Black also does not teach a formulation wherein "at least a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid" as required by Claims 1, 2, 6, 14-16, 21-24, 27, 28, 31, 32, and 36 of the present invention.

b. Independent Claim 37, Dependent Claims 38, 42, 51, 52, 56-59, 62, 63, 66, 67, and 71

Black does not teach "a drug of low water solubility" as required by Claims 37, 38, 42, 51, 52, 56-59, 62, 63, 66, 67, and 71 of the present invention.

Black also does not teach "a cellulosic polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 37, 38, 42, 51, 52, 56-59, 62, 63, 66, 67, and 71 of the present invention.

Black also does not teach a formulation having "at least a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid" as required by Claims 37, 38, 42, 51, 52, 56-59, 62, 63, 66, 67, and 71 of the present invention.

c. Independent Claim 72, Dependent Claims 73, 77-80, and 86-93

Black does not teach "a drug of low water solubility in a high energy phase" as required by Claims 72, 73, 77-80, and 86-93 of the present invention.

Black also does not teach "a turbidity-decreasing polymer in an amount effective to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 72, 73, 77-80, and 86-93 of the present invention.

As *Black* does not teach each and every element of the claims embracing the present invention, applicant requests withdrawal of the 35 U.S.C. 102(b) rejection.

C. Claim Rejections under 35 U.S.C. 103

The Examiner has rejected dependant claims under §103 without rejecting the independent claim from which such rejected claims depend. A dependent claim "shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim (See 37 C.F.R. 1.75; see also MPEP 608.01(i)). It is well settled that, [i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." In re Fine, 5 USPQ2d 1596 (Fed. Cir. 1988); see also MPEP 2143.03. Accordingly, the following analysis must include consideration of all limitations present in claims from which the each rejected claim depends.

1. Office has rejected Claims 4,5, 17-20,25, 26, 40, 41, 53-55, 60, 61, and 81-83 under 35 U.S.C. 103(a) as being unpatentable over Gao et al. (WO 00/32189) in view of Hanna et al. (USPN 4,601,894).

Applicant respectfully traverses Examiner's rejection and asserts that the claims, as currently presented, are non-obvious with respect to *Gao* in view of *Hanna*.

a. There is no motivation to combine the disclosure of Hanna with that of Gao.

According to MPEP 2142, one essential element necessary to establish a *prima-facie* case of obviousness is that there must be some suggestion or motivation, either in

the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In the present case, there is no motivation for one of ordinary skill in the art to combine the disclosure of *Hanna* with that of *Gao*.

Whereas the examiner has asserted that "[t]he prior art discloses a composition where the components are dissolved into the solvent liquid, it is the position of the examiner that *such limitations hold little patentable weight view of the prior art.*" [emphasis added], Applicant respectfully disagrees. MPEP 2141 mandates that "[t]he claimed invention must be considered as a whole." An analysis under 35 U.S.C. 103 cannot disregard claim limitations merely because the Office contends that "such limitations [to] hold little patentable weight

Gao teaches an orally deliverable celecoxib formulations capable of providing rapid relief from COX-2 mediated disorders. *Hanna* discloses a solid dosage formulation.

Applicant takes issue with the Examiner's characterization (Office Action dated 6 October 2003 on page 7, line 14-16) that "[t]he prior art discloses a composition where the components *are dissolved into the solvent liquid*, [emphasis added] . *Hanna* discloses only solid dosage formulations, which by definition, comprises neither solvent liquids or components dissolved therein. The distinction between solid and liquid dosage forms is fundamental. As such, one of ordinary skill in the art would have no motivation to combine the solid dosage forms of *Hanna* with the orally deliverable celecoxib formulations of *Gao* to make the present liquid dosage form.

As there is no explicit or implicit motivation for one of ordinary skill in the art to combine *Hanna* with *Gao*, the first criteria necessary for establishing a *prima-facie* case of obviousness has not been established. Accordingly, Applicant requests withdrawal of the 35 U.S.C. 103(a) rejection.

b. The references when combined do not teach or suggest all claim limitations required by the present invention.

According to MPEP 2142, one of the basic criteria required to establish a *prima-facie* case of obviousness is that the combined references must teach or suggest all the claim limitations. In the present case, the combination of *Gao* and *Hanna* does not teach or suggest all elements of the present invention and therefore no *prima-facie* case of obviousness has been established.

i. Dependent Claims 4,5, 17-20,25, and 26

The combination of *Gao* and *Hanna* does not teach or suggest "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" required by Claims 1, 4,5, 17-20,25, and 26 of the present invention. While *Hanna* discloses the polymer HPMC as a component of its formulation, and the present invention may comprise HPMC, *Hanna* does not teach or suggest any polymer "present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid."

ii. Dependent Claims 40, 41, 53-55, 60, and 61

The combination of *Gao* and *Hanna* does not teach or suggest "a cellulosic polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" required by Claims 37, 40, 41, 53-55, 60, and 61 of the present invention.

iii. Dependent Claims 81-83

The combination of *Gao* and *Hanna* does not teach or suggest "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" required by Claims 72 and 81-83 of the present invention.

The combination of *Gao* and *Hanna* does not teach or suggest "a drug of low water solubility in a high energy phase" as required by Claims 72 and 81-83 of the present invention.

Thus, the combination of *Gao* and *Hanna* does not teach or suggest all the claim limitations required by the present invention. Accordingly, applicant requests withdrawal of the 35 U.S.C. 103(a) rejection.

2. Office has rejected Claims 13 and 50 under 35 U.S.C. 103(a) as being unpatentable over Tanida et al. (WO 98/05310) or Gao et al. (WO 00/32189) in view of Guess et al. (USPN 6,054,455).

Applicant respectfully traverses Examiner's rejection and asserts that the claims, as currently presented, are non-obvious with respect either *Gao* and *Guess* or *Tanida* and *Guess*.

a. There is no motivation to combine the disclosure of Tanida or Gao with that of Guess.

In the present case, there is no suggestion or motivation to modify the reference or to combine reference teachings and therefore no *prima-facie* case of obviousness has been established.

On Page 8, lines 19-20 of the Office Action dated 6 October 2003, the Office states that, "[s]ince the compounds are so well known and well studies it would be well within the level of skill in the art to substitute the valdecoxib of *Guess* into the formulation of either *Tanida* or *Gao*."(emphasis added). According to the MPEP, a statement that modifications are "'well within the ordinary skill of the art' ... is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references." MPEP 2143.01 Quoting Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (emphasis added). Moreover, the level of skill in the art cannot be relied upon to provide the suggestion to combine references. Al-Site Corp. v. VSI Int'l Inc., 50 USPQ2d 1161 (Fed. Cir. 1999) (emphasis added). Absent a sufficient showing of a motivation to combine *Guess* with either *Gao* or *Tanida*, a *prima-facie* case of obviousness can not be established.

One of ordinary skill in the art would have no motivation to combine either the disintegration-protected of *Tanida* or the celecoxib formulations of *Gao* with the methods of using a neurokinin-1 receptor antagonist disclosed in *Guess* to create a rapid onset formulation of the present invention. Accordingly, applicant requests withdrawal of the 35 U.S.C. 103(a) rejection.

b. The references when combined do not teach or suggest all claim limitations required by the present invention.

In the present case, the combination of either *Gao* and *Guess* or *Tanida* and *Guess* does not teach or suggest all elements of the present invention and therefore no *prima-facie* case of obviousness has been established.

i. Dependent Claim 13

The combination of *Gao* and *Guess* or *Tanida* and *Guess* does not teach or suggest "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claim 13 of the present invention.

ii. Dependent Claim 50

The combination of *Gao* and *Guess* or *Tanida* and *Guess* does not teach or suggest "a cellulosic polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claim 50 of the present invention.

As the combination of *Gao* and *Guess* or *Tanida* and *Guess* does not teach or suggest all the claim limitations as required by the present invention. Accordingly, applicant requests withdrawal of the 35 U.S.C. 103(a) rejection.

3. Office has rejected Claims 29, 30, 64, 65, 84 and 85 under 35 U.S.C. 103(a) as being unpatentable over Tanida et al. (WO 98/05310).

Applicant respectfully traverses Examiner's rejection and asserts that the claims, as currently presented, are non-obvious with respect *Tanida et al.* (WO 98/05310).

a. The reference does not teach or suggest all claim limitations required by the present invention.

In the present case, the combined references do not teach or suggest all elements of the present invention and therefore no *prima-facie* case of obviousness has been established.

i. Dependent Claims 29 and 30

Tanida discloses oral preparations having a capsule base coated with successive layers of a cationic copolymer and an anionic copolymer where a pharmacologically active substance is encapsulated in the capsules.

Tanida does not teach or suggest "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 29 and 30 of the present invention.

Tanida also does not teach or suggest a formulation having "a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid" as required by Claims 29 and 30 of the present invention.

ii. Dependent Claims 64 and 65

Tanida does not teach or suggest "a cellulosic polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 64 and 65 of the present invention.

Tanida also does not teach or suggest a formulation having "a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid" as required by Claims 64 and 65 of the present invention.

iii. Dependent Claims 84 and 85

Tanida does not teach or suggest does not teach "a drug of low water solubility in a high energy phase" as required by Claims 84 and 85 of the present invention.

Tanida also does not teach or suggest "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claims 84 and 85 of the present invention.

Thus, *Tanida* does not teach or suggest all the claim limitations as required by the present invention. Accordingly, applicant requests withdrawal of the 35 U.S.C. 103(a) rejection.

4. Office has rejected Claim 76 under 35 U.S.C. 103(a) as being unpatentable over Tanida et al. (WO 98/05310) in view of Kawata et al. (USPN 4,343,789).

Applicant respectfully traverses Examiner's rejection and asserts that the claims, as currently presented, are non-obvious with respect *Tanida et al.* (WO 98/05310) in view of *Kawata et al.* (USPN 4,343,789).

a. There is no motivation to combine the disclosure of Tanida with that of Kawata.

In the present case, there is no motivation for one of ordinary skill in the art to combine the disclosure of *Tanida* with that of *Kawata*.

The *Kawata* reference, entitled "Sustained Release Pharmaceutical Composition of Solid Medical Material" discloses formulations containing an amorphous solid medical material, polyethylene oxide, and at least one basic substance selected from a Markush group.

A formulation prepared in accordance with *Tanida* is protected from disintegration until reaching the large intestine, normally between 5 and 9 hours after administration. See Figure 2 of *Tanida*

One of ordinary skill in the art would have no reason to combine the disintegration-protected formulations of *Tanida* with the sustained release formulations of *Kawata* to produce a rapid onset formulation as provided by the present invention.

As there is no motivation or suggestion provided in either *Tanida* or *Kawata* for one of ordinary skill in the art to combine the references, no *prima-facie* case of obviousness has been established. As such, withdrawal of the rejection the present application under 35 U.S.C. 103(a) is respectfully requested.

b. The references when combined do not teach or suggest all claim limitations required by the present invention.

The combination of *Tanida* and *Kawata* does not teach or suggest all the claim limitations required by the present invention, and therefore no *prima-facie* case of obviousness has been established.

The combination of *Tanida* and *Kawata* does not teach or suggest "a drug of low water solubility in a high energy phase" as required by Claim 76 of the present invention.

The combination of *Tanida* and *Kawata* also does not teach or suggest "a turbidity-decreasing polymer...present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid" as required by Claim 76 of the present invention.

The combination of *Tanida* and *Kawata* also does not teach or suggest a formulation where "a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid" as required by Claim 76 of the present invention.

Thus, the combination of *Tanida* and *Kawata* does not teach or suggest all the claim limitations as required by the present invention. Accordingly, applicant requests withdrawal of the 35 U.S.C. 103(a) rejection.

D. Provisional obviousness-type double patenting rejection

Office has provisionally rejected Claims 1, 2, 4-16, 21-28, 31-38, 41-46, 50-52, 56-59, 62, 63, 66-80, and 86-93 under the doctrine of obviousness-type double patenting over Claims 1-12, 18-20, and 24-32 of copending application no. 10/119,118.

The present claims are patentably distinct with respect to Claims 1-12, 18-20, and 24-32 of copending application no. 10/119,118.

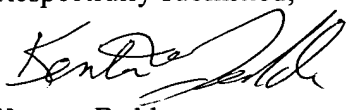
As this is a provisional rejection, and no conflicting claims in 10/119,118 ("'118") have been allowed at this time, a Terminal Disclaimer would be premature. Moreover, Applicant traverses the double patenting rejection because, among other reasons, Application '118 does not embrace the instant limitation of "a turbidity-decreasing polymer... in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug." Applicant respectfully submits that the double patenting rejection should be withdrawn without need for a Terminal Disclaimer.

E. Conclusions

In view of the foregoing, applicant believes that the present application is in condition for allowance.

If a telephonic interview with Applicant's representative would aid in the prosecution of this application, the Examiner is cordially invited to contact Applicant's representative at the below listed number.

Respectfully submitted,



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